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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,920	09/30/2003	Christopher P. Knapp	279.640US1	2079

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FAEGRE & BENSON LLP
PATENT DOCKETING - INTELLECTUAL PROPERTY (32469)
2200 WELLS FARGO CENTER
90 SOUTH SEVENTH STREET
MINNEAPOLIS, MN 55402-3901

EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	**PAPER NUMBER**
3762	

NOTIFICATION DATE	DELIVERY MODE
04/21/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/675,920	KNAPP ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,14-26,30-40 and 44-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 14-26, 30-40, and 44-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 5, 6, 9-11, 15, 16, 18, 21, 22, 25, 26, 35, 36, 39, 40, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Bolz et al. (US 5,964,794, hereinafter "Bolz").

3. In regards to claims 1, 16, and 35, Bolz discloses providing a pulse generator (Fig. 6); a lead having a body and conductor (Fig. 5); and an electrode (Fig. 8, element 1a) having a coating with a first layer adjacent the surface of the electrode (1b''' closest to 1a) including an insulative material (col. 9, lines 21-27), a second layer disposed over the first layer and not adjacent to the surface of the electrode (second 1b''' layer from electrode 1a), the layer including at least one pharmacological agent (1c'''), and a third layer disposed over the second layer (third 1b''' layer from electrode 1a), wherein the third layer includes at least one pharmacological agent (1c''').

4. In regards to claims 3, 18, and 36, the pharmacological agent is an anti-inflammatory (col. 9, lines 20-28).

5. In regards to claims 5, 6, 21, and 22, the first layer is a polymeric base coat (claim 2), and the second layer is a matrix of polymer and pharmacological agent (col. 9, lines 20-28).

6. In regards to claims 9, 10, 25, 39, and 44 the electrode further comprises a porous polymeric fourth layer (Fig. 8; "porous" because the drug molecules from the lower layers can escape) and is polymeric (claim 2, col. 6, line 22).

7. In regards to claims 11, 26, and 40, the fourth layer regulates release because the drug molecules from the lower layers must pass through the third layer.

8. In regards to claim 15, the first layer increases impedance (col. 9, line 24).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 30, 32, and 33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bolz. Bolz discloses the essential features of the claimed invention, including an outer layer in which the only

agent present is a pharmaceutical agent (i.e., "including only a pharmaceutical agent"). Alternatively, Bolz does not disclose that the outer surface is purely a pharmaceutical agent. It is well known in the implantable device arts to coat implants with pharmaceutical agents before implantation to provide the predictable results of delivering an effective amount of drug to acutely combat inflammation, infection, pain, or other potential complication with electrode placement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bolz's invention by coating the apparatus with only a pharmaceutical agent before implantation to provide the predictable results of delivering an effective amount of drug to combat inflammation, infection, pain, or other potential complication with electrode placement.

12. Claims 2, 4, 7, 8, 14, 17, 19, 20, 23, 24, 31, 34, 37, 38, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolz. Bolz discloses the essential features of the claimed invention except for a helical tip electrode, an anti-inflammatory of the claimed types, a base coat of ethylene vinyl alcohol, a pharmaceutical agent including an anti-proliferative drug, or applying the coatings by spraying. It is well known in the implantable device arts to provide helical tip electrodes to provide the predictable results of solid lead fixation, an anti-inflammatory of the claimed types to provide the predictable results of avoiding inflammation with known substances, ethylene vinyl alcohol in implantable devices to provide the predictable results of an implantable polymer with known biocompatability, a pharmaceutical agent including an anti-proliferative drug to provide the predictable results of avoiding the formation of scar

tissue around the electrode, and applying the coatings by spraying to provide the predictable results of ease of manufacturability of the electrode. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bolz's invention by providing helical tip electrodes to provide the predictable results of solid lead fixation, an anti-inflammatory of the claimed types to provide the predictable results of avoiding inflammation with known substances, ethylene vinyl alcohol in implantable devices to provide the predictable results of an implantable polymer with known biocompatability, a pharmaceutical agent including an anti-proliferative drug to provide the predictable results of avoiding the formation of scar tissue around the electrode, and applying the coatings by spraying to provide the predictable results of ease of manufacturability of the electrode.

13. Claims 47, 49, 50, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolz in view of Osypka et al. (US 7,187,980, herinafter "Osypka"). Bolz discloses the essential features of the claimed invention except for explicitly indicating a layer having up to 60% by weight of pharmacological agent. However, Osypka teaches an implantable drug-eluting electrode having a elution layer of up to 60% by weight of pharmacological agent (abstract -- "up to" including the range of 0-60%) to provide the predictable results of effectively controlling the long-term rate of drug release to the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bolz by providing an implantable drug-eluting electrode having a elution layer of up to 60% by weight of

pharmacological agent to provide the predictable results of effectively controlling the long-term rate of drug release to the patient.

14. Claims 46, 48, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolz in view of Weidlich et al. (US 5,103,837, hereinafter "Weidlich"). Bolt discloses the essential features of the claimed invention except for a first layer that is between 1 and 100 microns thick. However, Weidlich teaches a polymeric first layer that is between 1 and 100 microns thick (claims 16 and 17) to provide the predictable results of maintaining desired polarization properties, while still having a thin lead suitable for intracardiac placement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bolz by providing a polymeric first layer that is between 1 and 100 microns thick to provide the predictable results of maintaining desired polarization properties, while still having a thin lead suitable for intracardiac placement.

Response to Arguments

15. Applicant's arguments with respect to claims 1-11, 14-26, 30-40, and 44-52 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment. See paragraph 17 of the Office Action of 3/17/2008 for teachings of the various well-known elements cited above.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

/Scott M. Getzow/
Primary Examiner, Art Unit 3762